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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,052	04/05/1999	SHUJI SAITOH	981167	1182

23850 7590 04/06/2006

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/147,052	SAITOH ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26,32,33,39-41 and 44-46* is/are pending in the application.

4a) Of the above claim(s) *45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 26, 32, 33, 39-41 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed January 18, 2006 has been entered. Claims 25-26 and 32-33 have been amended. Claims 1-24, 27-31, 34-38 and 42-43 have been cancelled. Claims 45-46 have been withdrawn. Claims 25-26, 32-33, 39-41 and 44 are under consideration in this office action.

Response to Arguments

2. Applicant's arguments filed January 18, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The written description rejection of claims 25-26, 32-33, 39-41 and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record.

The rejection was on the grounds that the generic claims do not provide ample written description for fusion protein since the claims do not describe structural features

drawn to a dinucleotide or any larger oliogonucleotide encoding DNA, being the antigenic protein isolated from *Mycoplasma gallisepticum* and the signal polypeptide of Herpes virus glycoproteinB protein. Furthermore, the statements regarding the encoding DNA and the antigenic protein being isolated from *Mycoplasma gallisepticum* which cause an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum do not sufficiently provide ample written description since this only describes the function of the DNA and antigenic protein. Moreover, the rejection was on the grounds that the specification is limited to SEQ ID NO:1 and 3 since it does not provide examples of what qualify as a recombinant Avipox virus having DNA coding for a fusion protein.

Applicants' urge that the definition of the antigenic protein is based on a specific assayable characteristic that identifies them, thereby meeting the requirements of the written description requirement. However it is the examiner's position that the issue is not about whether one skilled in the art would know how to analyze the claimed characteristics of antigenic protein. The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. *In re Herschler*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir.1983). Applicants' have failed to show that they were in possession of the recombinant Avipox virus having a DNA coding for a fusion protein as instantly claimed.

For the written description requirement, an applicants' specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). The instant specification and claims describe a dinucleotide or any larger oliogonucleotide encoding DNA, being the antigenic protein isolated from *Mycoplasma gallisepticum* by its function i.e., causing an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum, however this description does not describe the claimed antigenic protein itself, nor does it provide the identity of the protein and the signal polypeptide of Herpes virus glycoproteinB protein.

Applicants' assert that the antigenic protein has been described by identifying characteristics and such identification is sufficient to satisfy the written description requirements. However, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying

characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). It is noted that functional limitations alone are not sufficient to satisfy the written description requirement.

Applicants' assert that other patents have similar wording, therefore, one skilled in the art would understand the scope and meaning of the recitation. However the prosecution of patents and the related applications is conducted in a case-by-case basis. It is irrelevant to rely on an unrelated patent where the prosecution history is unknown. Furthermore, applicants have not provided, beyond the misplaced reliance on other patents, evidence to refute the rejection. Finally, the fact that the recited patents have similar language, does not provide the instant case with a sufficient specification with respect to the written description rejection.

Applicants' urge that the function does not affect the recitation of the claims. However, the skilled artisan cannot envision the detailed structure of the antigenic protein, therefore, as applicants asserted, the skilled artisan would have to rely on identifying characteristics. These characteristics are the function of the antigenic protein, i.e., causing an antibody-antigen reaction. Therefore the antigenic protein itself is required. Without it, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the

invention. The characteristics the claimed antigenic protein only by what it does, are purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. Therefore, this description does not describe the claimed antigenic protein itself.

Applicants' assert that SEQ ID NO:1 and 3 are only exemplary and are not necessary for written description of the fusion protein. However it is the examiner's position that a lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process as is the case here. The MPEP states that for generic claims the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. Applicants' have failed to show a sufficient variety of representative recombinant Avipox viruses having a DNA coding for a fusion protein comprising an antigenic protein and a signal polypeptide. In *Gostelli,* the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618. The generic statements drawn to a dinucleotide or any larger oligonucleotide encoding DNA, do not provide ample written description for fusion protein. The specification does provide examples of what qualify as a recombinant Avipox virus having a DNA coding for a fusion protein, especially since applicants urge that SEQ ID NO:1 and 3 are not necessary for written description.

Furthermore, Applicants' have continuously pointed out throughout the prosecution of this case, recombinant Avipox viruses having a DNA coding for a fusion protein strains that do not meet the claimed limitations. Thus one of skill in the art could not immediately envision the claimed Avipox virus. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a disclosure of possible moieties does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). The functional limitations or characteristics do not constitute a written description of possible species in the genus because it would not "reasonably lead" those skilled in the art to any particular species. Therefore the rejection is maintained because applicants' arguments are not persuasive and because applicants' have failed to provide support that they were in possession of this Avipox virus as claimed.

Applicants' urge that a person skilled in the art could clearly recognize the gB signal polypeptide and the MG antigenic protein used in the claimed invention and understand the described structure of the fusion protein. However, it is the examiner's position that there is no disclosure of a generic recombinant Avipox virus having a dinucleotide or larger oligonucleotide or DNA coding for a fusion protein, comprising: (i) an antigenic protein isolated from *Mycoplasma gallisepticum* that causes an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum, and (ii) a signal polypeptide of Herpes virus glycoproteinB protein, said signal polypeptide being ligated with said antigenic protein isolated from *Mycoplasma gallisepticum* at the N terminus

thereof and there being no existence of a membrane anchor peptide such that said antigenic protein is secreted extracellularly, and wherein upon expression of said fusion protein in a host cell, said antigenic protein is secreted extracellularly. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Therefore applicants' arguments are not persuasive and the rejection is maintained.

7. The rejection of claims 25-26, 32-33, 39-41 and 44 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record. The rejection was on the grounds that the claims refer to "A recombinant Avipox virus having a DNA coding..." Therefore, the examiner presumed that applicant intends on having more than a single deoxyribonucleic acid. Applicants' urge that the commonly understood expression is understood by those skilled in the art and is an unnecessary change. However the claim language embraces acids the full-length sequence or any portion of the sequence. Thus claim is subject to a much broader interpretation then what applicants assert. Again the examiner points out that suggested that the claim language is "A recombinant Avipox virus having DNA coding." Accordingly, applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
March 27, 2006

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER